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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/544,664 | 04/06/2000 | Ziwei Huang | 8321-68 | 9219 |

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Daniel A Monaco
Drinker Biddle & Reath LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,664

Applicant(s)

HUANG ET AL

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 23-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Change of Art Unit Designation

1. **Please note:** The Art Unit location of this application in the PTO has changed from Art Unit 1642 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

Election/Restrictions

2. Applicant's election, with traverse, of Group I, claims 1-22, drawn to a novel carrier, e.g., a peptide-conjugate, for transporting the peptide across cell membranes, is acknowledged. Specifically, the invention is drawn to the elected (R-X)_n-peptide conjugate of: (C2-18 alkyl-CO)-SEQ ID NO: 56.

Applicant respectfully disagrees with the former Examiner's restriction requirement and finding that each of the conjugates ((R-X)-peptide) recited in alternative form is not a member of a single genus of the invention as well as the restriction of method groups II and III from conjugate/composition Group I. Absent a showing by Applicant that there is any core structure among the peptide SEQ ID NO.'s, this Examiner agrees with the former Examiner's determination that the individual peptides are necessarily independent and patentably distinct. The Examiner also agree in part, that the different R-X combinations are independent and distinct, since 8 different R- groups are distinctly different compounds each requiring a different structure search and imparting potentially different functionality on the peptide conjugate. However, this Examiner had removed the requirement that a specific "n" number of the elected R-X (C2-18 alkyl-CO) be elected, since a search for the elected R-X, even if found, can be further searched for repeating "n" of the elected R-X, without the need for a substantially

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different search of R-X. Thus, this Examiner has rejoined (C2-18 alkyl-CO)n1-10-SEQ ID NO: 56, as the elected conjugate of the invention. However, because the remaining aspects of the inventions are distinct for the reasons given above and the search required of one SEQ ID NO: with one R-X combination will not be the same for another R-X combination, or be the same for any of the other SEQ ID NO:'s and their respective R-X combinations; restriction for examination purposes as indicated is proper. The reasons for restriction by the former of Examiner of Groups I-III are also maintained by this Examiner, as Groups II and III differ in their objectives, steps, and parameters; and because a *text* search for the respective methods using related peptide conjugates would not be coextensive and would extend beyond the *structure and sequence* searches for the conjugate of Group I.

Notwithstanding the above, this Examiner undertook a review of the sequences submitted in the present application to determine if any of the other SEQ ID NO:'s contained any recognizable core sequence with SEQ ID NO: 56, which would it/them to be searched/ examined, without an undue burden, with elected SEQ ID NO: 56. It was found that SEQ ID NO: 55 contained core amino acid residues 1-27 of SEQ ID NO: 56, with the addition of LYS at residue 28. However, no other sequences bore any observable core sequence to SEQ ID NO: 56. Thus, Examiner has rejoined SEQ ID NO: 55, with 56, and examine the invention as drawn to either SEQ ID NO: 55 or 56.

Additionally, as will be shown below, a sequence database search of SEQ ID NO:'s 55 and 56 was conducted, wherein examination of the results found both SEQ ID NO:'s to be free of the prior art. Thus, in addition to examining the elected/rejoined R and X (C2-18 alkyl-CO)n1-10) compounds of the elected conjugate of Group I, Examiner has rejoined all R and X

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compound combinations of claim 1 with the elected invention conjugate, and examined the compound combinations as drawn to either SEQ ID NO: 55 or 56. [Had either SEQ ID NO: 55 or 56 been found, this would not have been permissible, since a search/examination of all the structurally different R- groups with either SEQ ID NO: 55 or 56, would have been unduly burdensome].

Rejections

35 U.S.C. § 112, 2nd

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 1 is drawn to a "peptide conjugate of the formula I: (R-X)_n-peptide. It is unclear what peptide is contemplated for use in the invention as the claim does not recite a specific SEQ ID NO: /NO: 's? Furthermore, as discussed above under the "Restrictions/ Elections" section, Applicant elected SEQ ID NO: 56, and the Examiner rejoined SEQ ID NO: 55.

To hasten prosecution, it is strongly suggested that independent claim 1 be amended by removing the "and" at the end of the paragraph discussing the "X" compound; adding "and" to the end of the paragraph discussing the "R" compound, and adding thereafter a new paragraph to the affect of "the peptide is selected from the group consisting of SEQ ID NO: 55 and SEQ ID NO: 56."

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b. Claim 10 is drawn to a peptide conjugate wherein the “peptide is a modulator of apoptosis”. It is unclear what is meant by the term “modulator”? The specification describes a peptide that is able to induce apoptosis by binding to Bcl-2, when Bcl-2 acts to inhibit apoptosis (see also claims 12-14). The term “modulate” does not define whether apoptosis is increased or decreased or somehow maintained at equilibrium; and any interpretation could be so attached. Thus, the claim is unclear, and Applicant is asked to distinctly claim in what way apoptosis is “modulated” by the peptide of claim 1.

c. Claims 10-14 are drawn to a peptide that both inhibits and induces apoptosis; namely where claim 10 inhibits apoptosis and claims 11-14 induce apoptosis. It is unclear whether how the peptide can both inhibit and induce apoptosis. The specification describes a peptide that is able to induce apoptosis by binding to Bcl-2, when Bcl-2 acts to inhibit apoptosis (see also claims 12-14); the nature of the invention. Applicant is asked to point out where in the specification the invention’s peptide is to be used to “inhibit” apoptosis. Alternatively, Applicant may overcome the rejection by canceling Claim 10.

d. Claim 18 is drawn to all peptides of SEQ ID NO: 1-57, and analogs thereof; and claim 19 is drawn to SEQ ID NO:’s 1, 30, 32, 34, 55, and 56. It is unclear what peptide constitutes the invention, based on the rejection of claim 1 and suggestions for amendment therein. As discussed above under the “Restrictions/ Elections” section, Applicant elected SEQ ID NO: 56, and the Examiner rejoined SEQ ID NO: 55. It is therefore suggested that claims 18-19 be cancelled based upon the suggested amendments to claim 1, as discussed above.

Conclusion

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4. As discussed above, the claimed invention has been examined over the art only insofar as it reads upon the elected and rejoined peptide sequences; i.e. SEQ ID NO.'s 55 and 56.

No prior art was found as of the time of this writing that taught with 100% homology SEQ ID NO.'s 55 and 56; and thus no prior art was found that taught the noted SEQ ID NO.'s with any of the compound combinations of claim 1. Thus, claim 1, in its entirety, as directed to SEQ ID NO.'s 55 and 56 is free of the art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Korsmeyer (US 5856445 (WO 98/17682, PCT/US97/19175)). Korsmeyer et al. is drawn to a substituted Bcl-2 polypeptide for use in apoptosis inducement. Korsmeyer et al. teach 100% homology of residues 3-27 of SEQ ID NO's: 55 and 56, but not 100% for either SEQ ID NO.'s in their entirety.

As part of the reply to this action, it is requested that Applicant submit a clean copy of the amended claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
May 19, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER